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SAFETY & EFFECTIVENESS DATA SUMMARY

Submitters Name, Address & Phone Number:

Nihon Seimitsu Sokki., Co., Ltd.
(Nissei)
2508-13, Nakago, Komochi-Mura
Kitagunma-Gun, Gunma-Ken
377-0293, Japan
+81-0279-20-2311

Submission Correspondent:

Lyle Howard Corporation
203 Main Street, 166
Flemington, NJ 08822
USA
Attention: Lynette Howard
908-788-4580

Classification Name: **Noninvasive Blood Pressure Monitor**
Common / Usual Name: **Blood Pressure Monitor**
Proprietary Name: **Model DS-1901 Digital Blood Pressure Monitor**

Establishment Registration Number: 9610827

Classification: **Class II, Reg. # 870.1130, DXN, Cardiovascular Devices Panel**

Performance Standards: **Sections 898 and 1010 of the Federal Food, Drug and Cosmetic Act**

Substantial Equivalence:

The legally marketed device to which substantial equivalence will be demonstrated is the Nissei Model DS-181 Digital Blood Pressure Monitor. This device was cleared for marketing under 510(k) No. K993890, SE decision December 3, 1999.

The subject device is essentially an updating of the predicate device. As can be seen in Appendix S, many of the features and performance specifications are identical. Note particularly that both systems contain a built-in air pump for automatic cuff inflation, have the same measurement accuracy for both blood pressure and pulse rate, are powered by four "AA" batteries, and include an optional AC adaptor.

The principal differences are that the new DS-1901 includes the circuit detecting arm circumference and the algorithm revising it to compensate the measurement result and to embody the application of a cuff to arm with circumference of 23 to 43 cm, which the predicate device DS-181 did not and that while the predicate device takes blood pressure measurement during deflation, the subject device takes measurement during inflation. "Personal mode", which determines inflation value from past measurements, is employed with new device. The clock function is also added to the subject device.

Because the difference between the subject device and the predicate device represent functional improvements that have been evaluated through both bench testing and clinical evaluation, it is clear that these changes raise no new questions with respect to either safety or effectiveness.

Testing conducted or standards applied to assure safety and effectiveness includes but is not limited to:

Clinical Performance and Accuracy: ANSI/AAMI Standard SP10-2002, Electronic or Automated Sphygmomanometers, approved October 28, 2002.

Electromagnetic Compatibility: IEC 60601-1-2, 2001 with test procedures according to IEC 61000-4-2, 2001; IEC 61000-4-3, 2001; IEC 6100-4-4, 2001 with Amendment 1, 2000 and Amendment 2,2001; IEC 6100-4-6, 2001; IEC 61000-4-8, 2001; IEC 61000-4-11, 2001.

Electromagnetic Interference: IEC 60601-1-2, 2001.

Description of the new device:

The Model DS-1901 Digital Blood Pressure Monitor is an automatic sphygmomanometer intended for measurement, including self-measurement by the patient, of systolic and diastolic blood pressure and pulse rate in adult patients in a homecare environment. Blood pressure is measured in the brachial artery using an arm cuff of the appropriate size. The unit includes an air pump for automatic cuff inflation, an electric valve, pushbutton controls, circuitry to detect and process minute pressure oscillations, an LCD display of systolic and diastolic blood pressure readings and pulse rate, a wide-ranged arm cuff and a carrying case. The memory circuit stores the thirty most recent readings plus the computed average of the stored readings, which will be retained after power turn-off or battery removal and can be intentionally deleted. The system is powered by four AA-size batteries or, optionally, by a 6V AC adapter.

Intended Use:

The DS-1901 system is intended for the noninvasive measurement of systolic and diastolic blood pressure and determination of pulse rate in adult patients, i.e., age 12 and above. The product is recommended for use by patients with labile blood pressure or know hypertension in a home care environment as an adjunct to medical management.

Safety and Efficacy Information:

The DS-1901 Blood Pressure Monitors are well recognized as being safe and effective for the stated intended use. The Nihon DS-1901 Blood Pressure Monitors have the same operating principals and intended uses as the predicate Blood Pressure Monitor systems already in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2005

Nihon Seimitsu Sokki, Co., Ltd. (Nissei)
c/o Dr. J. A. van Vugt
KEMA Quality B.V.
Utrechtseweg 310, 6812 AR
Arnhem
P.O. Box 5185, 6802 ED
Arnhem
THE NETHERLANDS

Re: K050697
Trade Name: Model DS-1901 Digital Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: March 17, 2005
Received: March 18, 2005

Dear Dr. van Vugt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050697

Indications for Use

510(k) Number (if known):

Device Name: Model DS-1901 Digital Blood Pressure Monitor

Indications For Use:

The DS-1901 system is intended for the noninvasive measurement of systolic and diastolic blood pressure and determination of pulse rate in adult patients, i.e., age 12 and above. The product is recommended for use by patients with labile blood pressure or know hypertension in a home care environment as an adjunct to medical management.

Prescription Use _____ AND/OR Over-The-Counter Use ___√___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050697